

**REMARKS**

**A. Introductory Remarks**

In view of the foregoing amendments and the following remarks, Applicants respectfully request reconsideration of the application.

Upon entry of the foregoing amendments, claims 1-54 will be pending in the application, with claims 3-5, 7-22, 24, and 26-53 being withdrawn from consideration. Claims 1, 6, 23, and 25 are amended. Claim 54 is being added. No claims are being canceled.

The following table identifies exemplary support for the amendments to each claim present in the specification.

Claim	Exemplary Support
1	Page 9, 14-16; page 11, lines 3-17; original claim 9
6	Page 9, lines 7-8 and 14-16
23	Page 9, lines 7-8 and 14-16; original claim 9; page 11, lines 3-17
25	Original claim 25; page 11, lines 3-17
54	Original claims 1 and 9; page 11, lines 3-17

It is acknowledged that the amendments are submitted after final rejection. However, because the amendments do not introduce new matter, and because the amendments either place the application in condition for allowance or at least in better condition for appeal, entry thereof by the Examiner is respectfully requested.

**B. The Markush Groups of Claims 1, 2, 23, and 25 are Proper**

Claims 1, 2, 23, and 25 remain objected to for allegedly reciting an improper Markush group. Office Action at pages 3-4. In maintaining the rejection, the Examiner referenced MPEP 803.02, which states, “[b]roadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that unity.” According to the Examiner, only some of the recited peptides share a HARL sequence, and “with respect to the functional ability to bind, the artisan would expect each of the peptides to exhibit distinct binding affinities.” Applicants respectfully traverse this ground for objection.

Contrary to the objection, unity of invention exists in amended claims 1, 2, 23, and 25 because the peptides recited in the Markush groups of the claims share a common utility and a substantial structural feature essential to that utility.

As noted in Applicants’ previous response, the peptides share functional characteristics that relate to their utility, including an ability to bind to neural thread protein (NTP).<sup>1</sup> This common characteristic, which is recited in the amended claims, contributes to the peptides’ usefulness in the range of diagnostic and therapeutic applications described throughout the specification. It also is exemplified in Examples 1, 2, and 4. Example 1 describes experiments showing that eight separate peptides containing Harlil sequences react with NTP. One of these, NTP-3, was selected for further studies and was shown to function as an affinity ligand for affinity purification of NTP (Example 2) and to be useful in assays for detecting and quantifying NTP (Example 4).

In relation to this common utility, all of the recited peptides share a substantial structural feature: an ARL peptide sequence derived from the “Harlil” motif in NTP. As taught throughout the specification, the Harlil motif provides unique and useful binding qualities to peptides.<sup>2</sup>

1.

<sup>1</sup> See page 5, lines 19-26 of the specification.

<sup>2</sup> See e.g., page 5, line 11 through page 6, line 14 of the specification.

Because every peptide recited in the Markush groups share a common utility and substantial structural feature relating to that utility, unity of invention exists among the members of the Markush groups. Therefore, Applicants respectfully request withdrawal of this ground for objection.

**C. Duplicate Claim Issue**

The Examiner advised Applicants that if claim 23 is found to be allowable, she will object to claim 25 under 37 C.F.R. 1.75 as being a substantial duplicate thereof. According to the Examiner, the claims have the same scope, despite linguistic differences between them. Applicants respectfully disagree.

Contrary to the Examiner's assertion, claims 23 and 25 differ in scope. Claim 23 recites 19 specific amino acid sequences, and embraces peptides having sequences that: (a) correspond exactly to the recited sequences, (b) comprise the recited sequences, (c) are homologs of the recited sequences, or (d) comprise homologs of the recited sequences. The peptides of claim 23 contain no more than 25 amino acids. In contrast, claim 25 recites only 5 specific amino acid sequences, and embraces peptides that comprise "at least one, but no more than 25 additional amino acids" flanking the recited sequences. Thus, the peptides of claim 25 contain up to 29 amino acids.

MPEP 706.03(k), which the Examiner cited, states: "court decisions have confirmed an applicant's right to restate (i.e., by plural claiming) the invention in a reasonable number of ways," and "a mere difference in scope between the claims has been held to be enough."

As claims 23 and 25 differ in scope, Applicants respectfully request that the Examiner withdraw this ground for objection to the claims.

**D. Claim 6 Complies with the Definite Claiming Requirement of 35 U.S.C. § 112, Second Paragraph**

Claim 6 remains rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite because the claim "appears to recite a peptide that is at most 29 residues in length," yet "also recites 'having' which is open language and would allow the peptide to be of greater

than 29 residues in length." Office Action at page 5. Applicants respectfully traverse the rejection.

As amended, claim 6 recites an isolated peptide comprising the amino acid sequence H A R L and *no more than* 21 additional amino acids. As such, the claimed peptide itself clearly contains no more than 25 amino acids. However, the peptide could contain additional non-amino acid elements or exist in a larger context. For instance, the peptide may be conjugated with a label or a linker molecule element. Additionally, the peptide may be conjugated to a larger molecule such as an immunoglobulin, as in Example 1. This would be clear to one skilled in the art reading claim 6 in light of the specification.

Accordingly, claim 6 complies with the definite claiming requirement of 35 U.S.C. § 112, second paragraph, and Applicants respectfully request withdrawal of the rejection.

**E. The Claims are Patentable over U.S. Patent 5,716,813 (Kubota)**

Claims 1-2, 6, 23, and 25 stand rejected under 35 U.S.C. § 102 as allegedly being anticipated by U.S. Patent No. 5,716,813 (Kubota) because, according to the Examiner, the patent teaches an isolated peptide of HARL in SEQ ID NO:8. Office Action at pages 5-6. Applicants respectfully traverse this ground for rejection.

The amended claims do not read on Kubota's peptide fragment. Claim 1 recites particular Harlil sequences that are not found in Kubota. Likewise, claims 6, 23, and 25 do not read on Kubota because they prescribe that any amino acid residues flanking a Harlil sequence correspond to sequences that flank a Harlil sequence in a neural thread protein. Kubota's HARL sequence is flanked by amino acid residues that do not correspond to those in neural thread protein. Therefore, Kubota does not anticipate the claimed invention, and Applicants request withdrawal of the rejection.

Applicants further note that Kubota does not render the claimed subject matter obvious because it provides no teaching or suggestion for modifying the HARL peptide sequence. In particular, it does not teach that HARL peptides have unique binding characteristic such as an affinity for NTP, an affinity for immunoglobulin, and an affinity for themselves.

**F. Claim 6 Complies with the Written Description Requirement of 35 U.S.C. § 112**

Claim 6 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In particular, the Examiner stated that the recitation "between one and 25" constitutes new matter absent evidence for support.

In view of amendments made to claim 6, the rejection is moot. In lieu of the "between one and 25" recitation, claim 6 now recites that the peptide comprises "no more than 21 additional amino acids." Exemplary support for this amendment exists in the specification at page 9, lines 14-16. That passage states that a Harlil peptide of the invention preferably "does not exceed 25 total amino acid residues in length." Accounting for the four H A R L residues of the claimed peptides, that allows for 21 additional amino acids.

Because the rejection is now moot, Applicants respectfully request its withdrawal.

**G. Concluding Remarks**

The present application is now in condition for allowance, and favorable reconsideration thereof is respectfully requested. If the Examiner believes that a telephone interview would advance prosecution, she is invited to contact the undersigned by telephone.

The Commissioner is hereby authorized to charge any additional fees that may be required for this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Atty. Dkt. No. 018792-0177  
Appln. No. 09/697,590

Respectfully submitted,

Date Nov 26, 2003

By Michele M. Simkin

FOLEY & LARDNER  
Washington Harbour  
3000 K Street, N.W., Suite 500  
Washington, D.C. 20007-5143  
Telephone: (202) 672-5538  
Facsimile: (202) 672-5399

Michele M. Simkin  
Attorney for Applicant  
Registration No. 34,717